



APPLICATION FOR A NEW RADIOACTIVE MATERIAL LICENSE AUTHORIZING MANUFACTURING AND DISTRIBUTION

The Virginia Department of Health (VDH) is requesting disclosure of all information for the purpose of obtaining a radioactive material license. Failure to provide any information may result in denial or delay of a radioactive material license.

Instructions – Complete all items. Refer to VAREG ORH-720 L, 'Guidance for Manufacturing and Distribution Licenses'. Use supplementary sheets where necessary. Retain one copy and submit original of the entire application to: Virginia Department of Health, Radioactive Materials Program, 109 Governor Street, Room 730, Richmond, VA 23219.

APPLICATION TYPE

Item 1 Type Of Application (Check box)

☐ New License

CONTACT INFORMATION

Item 2 Name and Mailing Address Of Applicant:

Item 3 Person To Contact Regarding Application:

Name:

E-mail:

Telephone Number (Include area code)

() - x

Applicant's Telephone Number (Include area code):

() - x

LOCATION OF RADIOACTIVE MATERIAL

Item 4 Location of Radioactive Material (Do not use Post Office Box):

(Attach additional pages if necessary)

Address:

Telephone Number (Include area code):

() - x

Address:

Telephone Number (Include area code):

() - x

Address:

Telephone Number (Include area code):

() - x

Are sources going to be used at other off-site locations? ☐ Yes ☐ No

If yes, please attach an additional sheet(s) with the locations (addresses) and a list of activities to be conducted at each location.

RADIATION SAFETY OFFICER

Item 5 Radiation Safety Officer (RSO) (Check all that apply)

- ☐ The name of the proposed RSO and other potential designees who will be responsible for ensuring that the licensee's radiation safety program is implemented in accordance with approved procedures.

RSO Name:

Tel (Include area code): () - X

E-mail:

AND

- ☐ The above named individual will perform all duties and responsibilities as listed in Appendix D of VAREG 'Guidance for Manufacturing and Distribution Licenses' and ensure proper oversight of the radiation safety program, including but not limited to, performing periodic on-site evaluations.

OR

- ☐ Alternative information is attached demonstrating how the listed individual will perform the duties and responsibilities and detailing how oversight of the radiation safety program will be conducted, including but not limited to, performing periodic on-site evaluations.

AND

- ☐ Before obtaining radioactive materials, the proposed RSO will have successfully completed training as described in the section titled "Radiation Safety Officer (RSO)" in VAREG 'Guidance for Manufacturing and Distribution Licenses'.

AND

- ☐ Before being named as the RSO, future RSOs will have successfully completed training as described in the section titled "Radiation Safety Officer (RSO)" in VAREG 'Guidance for Manufacturing and Distribution Licenses'.

OR

- ☐ Alternative information demonstrating that the proposed RSO is qualified by training or experience.

AUTHORIZED USERS AND TRAINING

Item 6 Authorized Users (Check box and attach requested information)

- ☐ We will attach a list of each proposed authorized user with the types and quantities of licensed material to be used and qualifications meeting the criteria described in the section titled "Authorized Users" in VAREG 'Guidance for Manufacturing and Distribution Licenses'.

OR

- ☐ We will attach a list of each proposed authorized user with the types and quantities of licensed material to be used and alternative information is attached demonstrating that each proposed authorized user is qualified by training and experience to use the requested licensed material.

Item 7 Training For Individuals Working In Or Frequenting Restricted Areas

(Occupationally exposed individuals and ancillary personnel) (Check box)

- ☐ A description of the radiation safety training program, including topics covered, groups of workers, assessment of training, qualifications of instructors and the method and frequency of training is attached.

RADIOACTIVE MATERIAL

Item 8 Radioactive Material (Attach additional pages if necessary)

UNSEALED SOURCES				
Radioisotope				
Chemical/Physical Form				
Maximum Possession Limit				
Proposed Use				

For volatile materials, specify whether the material will be free or bound and the requested possession limit for each form.

SEALED SOURCES

Radioisotope				
Sealed Source Manufacturer or Distributor and Model Number				
Device Manufacturer or Distributor and Model Number				
Maximum Possession Limit				
Proposed Use				

Note: If applicable, an evaluation or an emergency response plan is included for radionuclide(s) in excess of amounts listed in **12VAC5-481-3740**

FACILITIES AND EQUIPMENT

Item 9 Facilities And Equipment (Check box and attach requested information)

- ☐ A description is provided of the facilities and equipment at each location where radioactive material will be used. Diagrams should be drawn to a specified scale, or dimensions should be indicated. For facilities where it is anticipated that more than one laboratory or room may be used, a generic laboratory or room diagram may be submitted.

NOTE: See Appendix F of VAREG 'Guidance for Manufacturing and Distribution Licenses' for guidance.

AND, IF APPLICABLE

- ☐ A description showing the locations of shielding, the proximity of radiation sources to unrestricted areas, and other items related to radiation safety is provided.

AND/OR

- ☐ For radioactive materials that may become airborne, diagrams contain schematic descriptions of the ventilation systems, with pertinent airflow rates, pressures, filtration equipment, and monitoring systems. (Diagrams are attached)

RADIATION SAFETY PROGRAM

Item 10.1 Radiation Safety Program Audit

The applicant is not required to submit its audit program to the agency for review during the licensing phase. This matter will be examined during an inspection.

Item 10.2 Radiation Monitoring Instruments (Check one box)

- ☐ We will use instruments that meet the radiation monitoring instruments specifications published in Appendix I of VAREG 'Guidance for Manufacturing and Distribution Licenses'. We reserve the right to upgrade our survey instruments as necessary. The instruments will be calibrated by an organization licensed by VDH, the NRC or another Agreement State to perform calibrations.

OR

- ☐ We will use instruments that meet the radiation monitoring instrument specifications published in Appendix I of VAREG 'Guidance for Manufacturing and Distribution Licenses'. Additionally we will implement the model survey meter calibration program published in Appendix I of VAREG 'Guidance for Manufacturing and Distribution Licenses'. We reserve the right to upgrade our survey instruments as necessary.

OR

- ☐ We will provide a description of alternative equipment and/or procedures for ensuring that appropriate radiation monitoring equipment will be used during licensed activities and that proper calibration and calibration frequency of survey equipment will be performed. We reserve the right to upgrade our survey instruments as necessary.

Item 10.3 Material Receipt And Accountability (Check all that apply)

Unsealed Sources

- ☐ We will submit procedure(s) for ensuring radioactive material accountability.

Sealed Sources

- ☐ We will perform physical inventories at intervals not to exceed 6 month, to account for all sealed sources and devices received and possessed under the license. Records of inventories will be maintained for 5 years from the date of each inventory, and shall include the radionuclides, quantities, manufacturer's name and model numbers, location, individual performing inventory and the date of the inventory.

OR

- ☐ We will submit a description of the frequency and procedures for ensuring that no gauge has been lost, stolen or misplaced.

Item 10.4 Occupational Dosimetry (Check one box)

- ☐ We will maintain, for inspection by VDH, documentation demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10 percent of the allowable limits in **12VAC5-481-640**.

OR

- ☐ We will provide dosimetry processed and evaluated by a NVLAP-approved processor that is exchanged at a frequency recommended by the processor.

Item 10.5 Public Dose

No response is required in this license application; however, the licensee's evaluation of public dose will be examined during an inspection.

Item 10.6 Operating and Emergency Procedures (Check box)

- ☐ We will implement the operating and emergency procedures in Appendix K of VAREG 'Guidance for Manufacturing and Distribution Licenses'.

OR

- ☐ We will develop, implement and maintain safe use of radionuclides and emergency procedures that will meet the criteria in the section titled "Operating and Emergency Procedures" in VAREG 'Guidance for Manufacturing and Distribution Licenses'. (Procedures are attached)

Item 10.6.1 License Verification and Information (Check box and submit information)

- ☐ We will submit our procedures for verifying the license status before transfer and the regulatory information provided to the licensee upon transfer.

Item 10.7 Surveys (Check box)

- ☐ We will survey our facility and maintain contamination levels in accordance with the survey frequencies and contamination levels published in Appendix M of VAREG 'Guidance for Manufacturing and Distribution Licenses'.

OR

- ☐ We will submit alternative procedures. (Procedures are attached)

Item 10.8 Leak Test (Check all boxes that apply)

- ☐ Leak tests analysis will be performed by an organization authorized by VDH, the NRC or another Agreement State to provide leak testing services to other licensees; or by the licensee using a leak test kit supplied by an organization licensed by VDH, the NRC or another Agreement State to provide leak test kits to other licensees according to kit suppliers' instructions.

OR

- ☐ We will perform our own leak testing and sample analysis. We will follow the procedures in Appendix N of VAREG 'Guidance for Manufacturing and Distribution'.

OR

- ☐ We will submit alternative procedures. (Procedures are attached)
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Item 10.9 Maintenance

- ☐ We will develop, implement, and maintain procedures for maintenance of our devices which meets the criteria in the section "Maintenance" of VAREG 'Guidance for Manufacturing and Distribution Licenses' and, if applicable, in accordance to each manufacturer's recommendations and instructions. (Procedures are attached.)

AND

- ☐ Maintenance will only be performed by individuals who meet the qualifications described in "Maintenance" of VAREG 'Guidance for Manufacturing and Distribution Licenses'.

Item 10.10 Transportation

No response is needed from applicants during licensing phase. This matter will be examined during an inspection.

Item 10.11 Minimization of Contamination

No response is required if applicant meets the criteria in the following sections: "Radioactive Material", "Facilities and Equipment", "Operating and Emergency Procedures", "Surveys", "Leak Tests", and "Waste Management".

Item 10.12 Waste Management (Check all that apply)

- ☐ We will follow the model waste procedures published in Appendix P of VAREG 'Guidance for Manufacturing and Distribution Licenses'.
OR

- ☐ We will follow: ☐ Decay-In-Storage or ☐ Disposal of Liquids Into Sanitary Sewerage waste procedures that are published in Appendix P of VAREG 'Guidance for Manufacturing and Distribution Licenses'.

OR

- ☐ We will develop, implement and maintain procedures for waste collection, storage and disposal by any of the authorized methods described in Item 10.12 "Waste Management" of VAREG 'Guidance for Manufacturing and Distribution Licenses'. We will contact VDH for guidance to obtain approval of any method(s) of waste disposal other than those discussed in Item 10.12 "Waste Management" of VAREG 'Guidance for Manufacturing and Distribution'. (Procedures are attached)

OR

- ☐ If access to a radioactive waste burial site is unavailable, we will request authorization for extended interim storage of waste. We will refer to NRC IN 90-09 'Extended Interim Storage of Low-Level Radioactive Waste by Fuel Cycle and Materials Licenses', dated February 1990, for guidance and submit the required information with this applications.

IF SEALED SOURCES ARE USED

- ☐ We will return sealed sources/devices to the manufacturer, distributor or an organization licensed by VDH, the NRC or another Agreement State.

NOTE: Applicants do not need to provide information to VDH if they plan to dispose of LLW via transfer to another authorized recipient or to dispose of liquid scintillation media or animals containing low levels of H-3 or C-14 as authorized by **12VAC5-481-910**.

Item 10.13 Termination of Activities

- ☐ We will notify the agency, in writing, within 60 days of the decision to permanently cease radioactive material use per **12VAC5-481-510**.

SPECIFIC LICENSE FEE

Item 11 License Fees (Refer to **12VAC5-490**)

License fee enclosed:

- ☐ Yes Amount Enclosed: \$

CERTIFICATION (To be signed by an individual authorized to make binding commitments on behalf of the applicant.)

Item 12

I hereby certify that this application was prepared in conformance with **12VAC5-481 'Virginia Radiation Protection Regulations'** and that all information contained herein, including any supplements attached hereto, is true and correct to the best of my knowledge and belief.

SIGNATURE - Applicant Or Authorized Individual

Date signed

Print Name and Title of above signatory